K010754

AUG 1 5 2001

510(k) SUMMARY

Val Med's Nurse's Assistant O.R. Control System

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Val Med Corp.
4800 NW Saltzman Road
Portland, Oregon 97229
Telephone: (503) 614-1106
Facsimile: (503) 614-1109

Contact Person: Darko Spoljaric
Vice President

Date Prepared: March 13, 2001

Name of Device and Name/Address of Sponsor

Val Med Corp.
4800 NW Saltzman Road
Portland, Oregon 97229
Telephone: (503) 614-1106
Facsimile: (503) 614-1109

Common or Usual Name

Surgical Control Center

Classification Name

Accessory to a Ceiling Mounted Surgical Lamp
Accessory to a Medical Image Storage Device
Accessory to a Laparoscope, General & Plastic Surgery

Predicate Devices

Computer Motion's Hermes Operating Room Control Center
Olympus EndoAlpha
Karl Storz KSEA SCB-RUI
Hill-Rom, Inc.'s BrightStar©
American Sterilizer Co.'s Quantum©, SQ24

Getinge/Castle, Inc. OptiView©, 500 series

Intended Use / Indications for Use

The Val Med Nurse's Assistant is intended to be used to turn on and off and adjust certain settings of endoscopic and surgical cameras, surgical lamps, and operating room ("O.R.") lights, and to operate VCRs, monitors, video printers, radios, and CD players.

The Val Med Nurse's Assistant is indicated for use in general, cardiovascular, ENT, gastroenterology, urology, plastic, obstetrics, gynecology, and orthopedic surgery, and general thorascoscopy, general cardiothoracic surgery, general laparoscopy, nasopharyngoscopy, ear endoscopy, and sinuscopy. A few examples of the more common surgical procedures where this system could be used are laparoscopic cholecystectomy, laparoscopic hernia repair, laparoscopic appendectomy, laparoscopic pelvic lymph node dissection, laparoscopically assisted hysterectomy, laparoscopic and thorascopic anteriorspinal fusion, decompression fixation, wedge resection, lung biopsy, pleural biopsy, dorsal sympathectomy, pleurodesis, internal mammary artery dissection for coronary artery bypass, coronary artery bypass grafting where endoscopic visualization is indicated, examination of the evacuated cardiac chamber during performance of valve replacement, arthroscopic meniscus repair, anterior cruciate ligament repair and associated procedures.

Performance Data

The Nurse's Assistant's control unit meets EN 60601-1 Medical Electrical Equipment Part 1: General Requirements for Safety 4: Collateral Standard: Programmable Electrical Medical Systems.

The Nurse's Assistant's power supply meets UL 2601-1 "U.L. Standard for Safety for Medical Electrical Equipment – General Requirements for Safety".

The Nurse's Assistant's controlling software meets ANSI standard 1375-221.

Technological Characteristics

The Val Med's Nurse's Assistant is a computer with a monitor and touch screen that a nurse uses in the operating room to activate and control the following equipment: (1) surgical cameras, including an endoscopic camera;

(2) room or surgeons'/nurses' lounge cameras ("operating room cameras");[1] (3) surgical lights; (4) room lights; (5) a VCR;[2] (6) a video printer; (7) video monitor(s);[3] (8) a radio; and (9) a CD player.[4] Val Med's Nurse's Assistant controls one or more electrical dimmer switches, which in turn control the surgical lights.

Substantial Equivalence

The Nurse's Assistant has the same intended use and similar indications for use and technological characteristics as its predicate, Computer Motion's Hermes Operating Room Control Center, the Olympus EndoAlpha, and the Storz KSEA SCB-RUI. In addition, the surgical lamp that is used with the Nurse's Assistant is substantially equivalent to Hill-Rom, Inc.'s BrightStar©, American Sterilizer Co.'s Quantum©, SQ240, and Getinge/Castle, Inc. OptiView©, 500 series. Therefore, the Nurse's Assistant is substantially equivalent to its predicate devices.

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1 We believe that these surgical cameras are Class I exempt devices, under 21 C.F.R. § 878.4160.

2 We believe that the VCR is a medical image storing device under 21 C.F.R. § 892.2010(a), which is, therefore, a Class I exempt storage device. Alternatively, it is not a medical device, subject to FDA regulation.

3 We believe that these monitors are accessories to medical image communications devices. As such, theses monitors are Class I exempt from 510(k) requirements under 21 C.F.R. § 892.2020(a), which states that a "medical image communications device" provides "electronic transfer of medical images between medical devices."

4 We have not been able to identify any device classification regulations that encompass operating room lights, operating room cameras, speakerphones, radios, and CD players nor have we identified any cleared devices like these products. For this reason, we believe that these products are not medical devices and the company will not make medical claims related to these components.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 5 2001

Val Med Corporation
c/o Mr. Howard M. Holstein, Esq.
Hogan & Hartson L.L.P.
555 Thirteenth Street, N.W.
Columbia Square
Washington, D.C. 20004

Re: K010754
Trade/Device Name: Val Med Corporation Nurse's Assistant
O.R. Control System
Regulation Number: 876.1500, 876.1500, 876.1500, 878.4580, 884.1720
Regulatory Class: II
Product Code: GCJ, KOG, FET, FSY, HET
Dated: July 5, 2001
Received: July 5, 2001

Dear Mr. Holstein:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K010754

Device Name: **Val Med Corp. Nurse's Assistant O.R. Control System**

Indications for Use:

The Nurse's Assistant is intended to be used to turn on and off and adjust certain settings of endoscopic and surgical cameras, surgical lamps, and operating room ("O.R.") lights, and to operate VCRs, monitors, video printers, radios, and CD players.

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(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use____
(Per 21 C.F.R. 801.109)

Mark N Milhern

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K010754

(Optional Format 1-2-96)